



PATENT
Application Serial No. 09/382,837
Applicant's Reply Brief Under 37 C.F.R. § 41.41

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appl. No. : 09/382,837
Applicant(s) : Borodic, Gary E.
Filed : August 25, 1999
TC/A.U. : 1644
Examiner : Gerald R. Ewoldt
Docket No. : 33677-00600US
Customer No. : 000038647
Title : *Chemodenervating Pharmaceutical As
Anti-Inflammatory Agent*

**MAIL STOP APPEAL BRIEF – PATENTS
COMMISSIONER OF PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450**

**REPLY BRIEF TO THE BOARD OF PATENT APPEALS AND
INTERFERENCES UNDER 37 C.F.R. § 41.41**

In response to the Examiner's Answer dated March 5, 2007, Applicant respectfully submits the following Reply Brief and Request for Oral Hearing dated May 7, 2007 (May 5, 2007 having fallen on a Saturday). Applicant believes the Reply Brief and Request for Oral Hearing to be timely filed within two months from the mail date of the Examiner's Answer. Accordingly, no extension of time is necessary.

In view of the following arguments, Applicant respectfully requests reconsideration and allowance of the pending claims.

I. STATUS OF CLAIMS

Claims 1, 5-8, 10-12, 24, 25 and 42-57 are pending and presently on appeal.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1, 5-8, 24, 25, 42, 43 and 46-57 are unpatentable under 35 U.S.C. § 112, first paragraph, as being based on a nonenabling disclosure of “a method of reducing inflammation without causing muscle weakness.”
2. Whether claims 10-12 are unpatentable under 35 U.S.C. § 103 over U.S. Pat. No. 6,063,768 in view of the Merck Manual.
3. Whether claims 1, 5-8, 10-12, 21-25 and 42-57 are unpatentable under 35 U.S.C. § 112, first paragraph, as being based on a disclosure lacking written description support for the claimed invention.

III. ARGUMENT

On April 30, 2007, the Supreme Court issued its decision in *KSR Int'l. Co. v. Teleflex, Inc.*, No. 04-1350 (US April 30, 2007). On May 3, 2007, the USPTO issued preliminary guidance to the patent examining corps in view of the *KSR* decision (copy attached). Applicants submit the instant Reply Brief to address the decision in *KSR* and the subsequent guidance issued by the USPTO. Entry of the Reply Brief is respectfully requested.

In *KSR*, the Supreme Court rejected the notion that the obviousness concept in patent law can be rigidly or narrowly defined, holding that “the obviousness analysis cannot be confined by a formalistic conception.” (p. 15). The Supreme Court reaffirmed the obviousness test set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966) and pointed out that *Graham* provides an expansive and flexible approach to the obviousness question. The Court acknowledged that in the appropriate circumstance, the “teaching, suggestion, or motivation” test is an acceptable approach to assess obviousness and that there is no necessary inconsistency between the Federal Circuit's “teaching, suggestion, or motivation” test and the *Graham* analysis. The Court noted that since the TSM test was devised, the Federal Circuit doubtless has applied it in accord with these principles in many cases. (*Id.* at 15). While not a requirement, the “TSM test may still be considered in the appropriate circumstances.”

The Court affirmed that a patent composed of several elements is not made obvious merely by showing that each element was, independently, known in the prior art. (p. 14). Although common sense directs caution as to a patent application

claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. (p. 14-15). Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known. (p. 15). The Court also acknowledged the risk and distortion caused by hindsight bias and warned that a fact finder must be cautious of arguments reliant upon ex post reasoning. (p. 17).

However, the Supreme Court warns that a court errs where, as in *KSR*, it transforms general principles and helpful insights into a rigid rule. (p. 15). Rigid preventative rules that deny recourse to common sense are neither necessary, nor consistent, with its case law. (p.17). The Supreme Court corrects the Federal Circuit on three specific legal points, stating that any need or problem known in the field of endeavor can provide a reason for combining the elements in the manner claimed, not just the motive of the patentee. (p. 16); that in many cases a person of ordinary skill will not just look to patents designed to solve the same problem, but be able to fit the teachings of multiple patents together (pp. 16-17); and that the fact that a combination was obvious to try might in some but not all circumstances show that it was obvious under §103 (for example when there is a design need or market pressure to solve a problem, and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp). (p. 17). The Supreme Court highlighted that the patentee in *KSR* had

not shown anything in the prior art that *taught away* from the use of the prior art at issue, nor any secondary factors, thus affirming that these continue to be important components in the overall obviousness inquiry. (p.22).

The Federal Circuit itself, in expectation of the impending Supreme Court decision in *KSR*, recently adopted a more flexible approach to its obviousness analysis. In *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007), the Federal Circuit described its TSM test as subsumed within the Graham factors as a subsidiary requirement. *See Id.* at 1361. The Court relied on its recent opinion in *Daystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006) to find a motivation to combine references not only from the prior art as a whole, but also from common knowledge and the nature of the problem to be solved. *See Pfizer* at 1362. The Federal Circuit noted that “obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.” *See Id.* at 1364. In particular, the Court characterized the work of the Plaintiff-Appellee as “routine testing”, conducted to merely verify an expectation of success, in contrast to trial and error procedures that support true discovery. *See Id.* at 1367.

The Supreme Court continues to recognize that it is wholly improper to use hindsight, and it is still impermissible for an expert to use hindsight and expertise, rather than the knowledge of an ordinary skilled person, to try to find their own way through the maze of alternate paths that faced persons of ordinary skill in the art at the time of an invention. *See KSR* at 17. *KSR* allows a person of ordinary skill to look at a

variety of needs or problems known in the field, and when there are a small finite number of identified, predictable solutions, such a person may have good reason to pursue known options. *See Id.* at 16-17.

But those are not the facts in the claims at issue in this case. As the Examiner's Answer acknowledges, the '768 patent differs from the claimed invention because it does not teach a method of reducing inflammation due to blepharoconjunctivitis, hay fever, rhinitis, or type 1 hypersensitivity. Neither does the '768 patent teach or suggest the use of botulinum toxin for treating allergic forms of eczema, urticaria or inflammatory bowel disease. The Merck manual does not cure these deficiencies. Thus, the Office has not met its burden of establishing a *prima facie* case of obviousness under any standard. As the USPTO's guidance to examiner's explains, "the Court did not totally reject the use of 'teaching, suggestion, or motivation' as a factor in the obviousness analysis." Thus, Applicants respectfully request that the rejection be withdrawn.

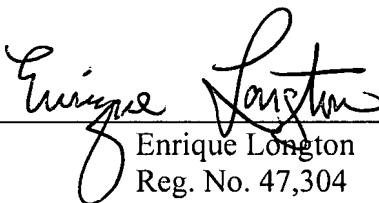
Conclusion

Applicants respectfully request reconsideration and withdrawal of the pending rejections and early allowance of the pending claims.

The Commissioner is authorized to charge any additional fees associated with this brief, or credit any overpayment, to Deposit Account No. 13-3250. **EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 13-3250. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with C.F.R. § 1.136(a)(3).

Respectfully submitted,

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Dated: May 7, 2007

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MEMORANDUM

DATE: May 3, 2007

TO: Technology Center Directors

FROM: *Margaret A. Focarino*
Margaret A. Focarino
Deputy Commissioner
for Patent Operations

SUBJECT: Supreme Court decision on *KSR Int'l. Co., v. Teleflex, Inc.*

The Supreme Court has issued its opinion in *KSR*, regarding the issue of obviousness under 35 U.S.C. § 103(a) when the claim recites a combination of elements of the prior art. *KSR Int'l Co. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 2007). A copy of the decision is available at <http://www.supremecourtus.gov/opinions/06pdf/04-1350.pdf>. The Office is studying the opinion and will issue guidance to the patent examining corps in view of the *KSR* decision in the near future. Until the guidance is issued, the following points should be noted:

- (1) The Court reaffirmed the *Graham* factors in the determination of obviousness under 35 U.S.C. § 103(a). The four factual inquiries under *Graham* are:
- (a) determining the scope and contents of the prior art;
 - (b) ascertaining the differences between the prior art and the claims in issue;
 - (c) resolving the level of ordinary skill in the pertinent art; and
 - (d) evaluating evidence of secondary consideration.

Graham v. John Deere, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

- (2) The Court did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

- (3) The Court rejected a rigid application of the "teaching, suggestion, or motivation" (TSM) test, which required a showing of some teaching, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the prior art elements in the manner claimed in the application or patent before holding the claimed subject matter to be obvious.

(4) The Court noted that the analysis supporting a rejection under 35 U.S.C. § 103(a) should be made explicit, and that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. The Court specifically stated:

Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**.

KSR, slip op. at 14 (emphasis added).

Therefore, in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.